

§ 520.1157

(iii) *Limitations.* For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 50 milligrams twice daily.

(ii) *Indications for use.* Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992]

§ 520.1157 Iodinated casein tablets.

(a) *Specifications.* Each 1-gram tablet contains 25 milligrams of iodinated casein.

(b) *Sponsor.* See No. 017762 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* $\frac{1}{5}$ to 1 tablet per 10 pounds of body weight (equivalent to 0.5 to 2.5 milligrams of iodinated casein per pound of body weight).

(2) *Indications for use.* For dogs for apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, seborrhea, thickening of the skin, hyperpigmentation, and lethargy.

(3) *Limitations.* If no response is observed in 30 to 45 days, the drug should be withdrawn and the diagnosis reconsidered. Do not use in the presence of cardiac disease, ischemia, adrenal insufficiency, or nephrosis. Federal law

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restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 22469, May 30, 1984]

§ 520.1158 Iodochlorhydroxyquin boluses.

(a) *Specifications.* Each bolus contains 10 grams of iodochlorhydroxyquin.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 1 bolus (10 grams) daily for a 1,000-pound horse.

(2) *Indications for use.* For treatment of equine diarrhea.

(3) *Limitations.* For horses only; not to be administered to food-producing animals. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 8054, Feb. 25, 1983, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.1182 Iron dextran oral suspension.

(a) *Specifications.* Each 1.8 milliliter contains 100 milligrams of elemental iron as ferric hydroxide in complex with a low molecular weight dextran and 0.2 percent phenol as a preservative.

(b) *Sponsor.* See 017800 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 100 milligrams of elemental iron to each pig.

(2) *Indications for use.* Prevention of iron deficiency anemia in baby pigs.

(3) *Limitations.* Treat each pig within 24 hours of farrowing. Administer 1.8 milliliters orally by automatic dose dispenser.

[45 FR 75199, Nov. 14, 1980]

§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.0187 mg (1.87 percent) or 0.00153 mg (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) No. 050604 for use of a 1.87-percent paste as in (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section and a 0.153-percent paste for use as in paragraph (e)(2) of this section.

(2) Nos. 051311 and 059130 for use of a 1.87-percent paste for use as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

(3) No. 061623 for use of a 1.87 percent paste for use as in paragraph (e)(1)(i), (e)(1)(ii)(C), and (e)(1)(iii) of this section.

(c) *Related tolerances.* See §556.344 of this chapter.

(d) *Special considerations.* See §500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use.* For treatment and control of:

(A) Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults), *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(B) Large Strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus edentatus*), (adult

(*Triodontophorus* spp.); Small Strongyles, including those resistant to some benzimidazole class compounds (adult and fourth-stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); Pinworms (adult and fourth-stage larvae) (*Oxyuris equi*); Ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostrongylus axei*); Large mouth Stomach Worms (adult) (*Habronema muscae*); Stomach Bots (oral and gastric stages) (*Gasterophilus* spp.); Lungworms (adults and fourth-stage larvae) (*Dictyocaulus arnfieldi*); Intestinal Threadworms (adults) (*Strongyloides westeri*); Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and Dermatitis caused by neck threadworm microfilariae (*Onchocerca* sp.).

(C) Large strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, and *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., and *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; Intestinal Threadworms (adults)—*Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(iii) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amount*. 23 milligrams per 250 pounds of body weight.

(ii) *Indications for use*. It is used in cattle for the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (*Ostertagia ostertagi* (including inhibited forms), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum*, *Trichuris ovis* (adults only)); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (first, second, and third instars) (*Hypoderma bovis*, *H. lineatum*); and sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*).

(iii) *Limitations*. For oral use only. Do not treat cattle within 24 days of slaughter. Because withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

[49 FR 22275, May 29, 1984, as amended at 50 FR 27819, July 8, 1985; 51 FR 44449, Dec. 10, 1986; 53 FR 51273, Dec. 21, 1988; 62 FR 63270, Nov. 28, 1997; 65 FR 70661, Nov. 27, 2000; 67 FR 71820, Dec. 3, 2002; 68 FR 43294, July 22, 2003; 69 FR 59131, Oct. 4, 2004; 70 FR 8514, Feb. 22, 2005]

§ 520.1193 Ivermectin tablets and chewables.

(a) *Specifications*. (1) Each tablet or chewable contains 68, 136, or 272 micrograms (mcg) ivermectin.

(2) Each chewable contains 55 or 165 mcg ivermectin.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 050604 for use of tablets or chewables described in paragraph (a)(1) as in paragraph (d)(1) and chewables described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(2) Nos. 051311 and 059130 for use of tablets described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*. For use in dogs 6 weeks of age and older as follows:

(i) *Amount*. 6.0 mcg per kilogram (kg) of body weight (2.72 mcg per pound

(lb)), minimum. Up to 25 lb, 68 mcg; 26 to 50 lb, 136 mcg; 51 to 100 lb, 272 mcg; over 100 lb, a combination of the appropriate tablets. Administer at monthly dosing intervals.

(ii) *Indications for use*. To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

(2) *Cats*. For use in cats 6 weeks of age and older as follows:

(i) *Amount*. Up to 2.3 kilograms (up to 5 lb), 55 mcg; 2.3 to 6.8 kilograms (5 to 15 lb), 165 mcg; over 6.8 kilograms (15 lb), a combination of the appropriate chewables (recommended minimum dose of 24 mcg/kg of body weight (10.9 mcg/lb)). Administer once a month.

(ii) *Indications for use*. To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense*.

[67 FR 11230, Mar. 13, 2002, as amended at 67 FR 21996, May 2, 2002; 69 FR 43735, July 22, 2004]

§ 520.1194 Ivermectin meal.

(a) *Specifications*. Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations*. See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) *Amount*. Administer 136 micrograms (mcg) ivermectin per pound (lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) *Indications for use*. For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*,